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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SAJJADI, FEREYDOUN GHOTB	
ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No.	Applicant(s)	
	10/502,224	RAO ET AL.	
	Examiner	Art Unit	
	FEREYDOUN G. SAJJADI	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *5-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 28, 2008 that includes a response to the advisory action dated March 18, 2008, has been entered. Claims 1-10 are pending in the Application. Claims 5-10 remain withdrawn from consideration, with traverse. Claim 1 has been amended. No claims were cancelled or newly added.

Claims 1-4 are currently under examination.

Claim Objection

Claim 10 is objected to because of the following informalities: The claim recites: "under conditions in which other populations differentiate into neurons or oligodendrocytes but not oligodendrocytes". The phrase "but not oligodendrocytes" should precede the quotation, following "generating astrocytes", as presented in the amendment dated February 2, 2008; because the cells cannot at once differentiate into oligodendrocytes but not oligodendrocytes. Further, "the other populations" needs to be specified as either astrocyte restricted, mammalian fetal tissue, ES cell cultures, or glial cell cultures. Appropriate correction is required.

New Claim Rejections - 35 USC § 112- New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicants' claim amendments have necessitated the following new grounds of rejection.

Claim 1 is newly rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art (hereafter the Artisan), that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR §1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Comment [a1]: For RCE practice, we do not make the RCE Final if new rejections are added, particularly new matter rejections. Look at it this way, if they had filed this as an after-final you would not have entered it and so the RCE gives them the opportunity for additional consideration.

Claim 1recites the limitation: "generating astrocytes…under oligodendrocyte differentiation conditions of plating in a bFGF-containing medium for 2 days and then switching to a medium containing PDGF or exposure to PDGF and thyroid hormone". The instant specification is devoid of any such description for the claimed limitation. Applicants state that support for the amendment can be found in the specification on p. 17, lines 10-14, wherein the oligodendrocyte differentiation conditions set forth in claim 1 are specifically taught. However, as admitted by Applicants, the conditions recited in both claim 1 and the specification are specific for oligodendrocyte differentiation, and not for generating astrocytes, as required by the claim. The specification continues in lines 15-17 of p. 17: "For astrocyte differentiation, cells were cultured for 5 days in the presence of fetal calf serum (10%, Life Technologies)". Thus, the specification fails to provide support for generating astrocytes under oligodendrocyte differentiation conditions. The conditions claimed are for oligodendrocyte differentiation, yet the base claim is directed to astrocyte restricted precursor cells that generate astrocytes but not oligodendrocytes. The specification fails to disclose the production of astrocytes under oligodendrocyte differentiationg conditions.

Claim 1 additionally recites: "generating astrocytes under conditions in which other populations differentiate into neurons or oligodendrocytes". Applicants state that such is not in accordance with teachings at page 8 of the specification. However, p. 8, lines 26-28, with reference to astrocyte restricted precursor cells, states: "population of cells does not express A2B5 and differs from stem and progenitor cell populations in its expression of CD44 and its ability to differentiate into astrocytes". Thus, the disclosure of the specification is not

synonymous with the limitation of the instant claim, i.e. other population of any cell types, and does not implicitly encompass any types of other cells.

Thus, at the time the application was filed, an Artisan of skill would not recognize from the disclosure that Applicant was in possession of conditions for generating astrocytes under conditions of oligodendrocyte differentiation, or other populations of any cell types, as claimed.

This is a new matter rejection.

Response to Claim Rejections - 35 USC § 112 - Enablement

Claims 1-4 stand rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. The rejection set forth on pp. 3-8 of the previous office action dated November 1, 2007 is maintained in modified form, for reasons of record, because the specification while being enabling for a culture of mammalian neural progenitor cells from embryonic or fetal tissue, or a culture of mammalian ES cells that may be differentiated into astrocytes, oligodendrocytes and neurons under appropriate differentiation conditions, does not reasonably provide an enablement for a pure homogenous population of mammalian astrocyte restricted precursor cells, being CD44 immunoreactive and generating astrocytes but not oligodendrocytes, or a method of isolating the same from embryonic or fetal tissue, ES cell cultures, or glial restricted precursor cells, as broadly claimed.

The previous office action dated March 17, 2007 set forth issues with regards to the deficiencies in the instant specification in providing an enabling disclosure for the instantly claimed cells and methods, and indicating an absence of an enabling disclosure for a pure homogeneous population of mammalian astrocyte restricted precursor cells, being CD44 immunoreactive and generating astrocytes but not oligodendrocytes, or a method of isolating the same from embryonic or fetal tissue, ES cell cultures, or glial restricted precursor cells, because the specification states: "The astrocyte restricted precursor cells of the present invention do not express A2B5. Further these cells differ from stem and progenitor cell populations in their expression of CD44 and their ability to differentiate into astrocytes…but not oligodendrocytes" (lines 14-25, p. 4), that is not accord with the observations in the working examples. The

examples show that at least for the human neuroepithelial progenitor cells, it is clear that following marker sorting, the same cell population may be differentiated to give rise to astrocytes, oligodendrocyte and neurons, depending on alterations in culture conditions. Hence, the human neuroepithelial progenitor cells are not astrocyte restricted, as they may differentiate into additional cells types. Moreover, the progenitor cells are capable of differentiation into oligodendrocytes, as taught by the specification, contrary to the language of the instant claims.

Applicants traverse the rejection, arguing they disagree with the Examiner's characterization of Lodie et al. as a prior art reference and its teachings with respect to the instant invention, as it was published in the October 2002, and its teachings relate to adult human bone marrow derived stem cells, in contrast to the instant application drawn to precursor cells being isolated from mammalian embryonic or fetal tissue, mammalian embryonic stem (ES) cell cultures or glial restricted precursor cells; thus whether CD44 expression is variable is irrelevant. Applicants' arguments have been fully considered, but are not found persuasive.

Lodie et al. (Oct. 2002) was not cited as a prior art reference. Lodie et al. disclose that in human bone marrow derived stem cells, CD44 expression is variable, and apparently dependent on serum concentration (Abstract). The authors further demonstrated that CD44 expression did not have an impact on the ability of the cells to ultimately differentiate toward the neural lineage and appeared to be dependent on serum concentration as demonstrated by other researchers (pp. 749-750, bridging). Lodie et al. additionally state that stromal and mesenchymal stem cells have additionally been isolated from bone marrow and have the capacity to differentiate along all different cell lineages, including the neural lineage. The instant claims encompass fetal tissue precursor cells that are CD44 immunoreactive and generate astrocytes under appropriate differentiation conditions. These cells necessarily encompass mesenchymal stem cells present in fetal cord blood, and Applicants have not provided any evidence that the CD44 immunoreactive mesenchymal stem cells disclosed by Lodie are structurally or functionally distinct from those of fetal mesenchymal stem cells.

Moreover, while Applicants should not rely on post-filing art to provide an enablement for their as filed disclosure, the art of Lodie et al. was provided to show the unpredictability and lack of enablement present in certain embodiments of the instantly claimed invention. As stated

in MPEP 2164.05(a), If individuals of skill in the art state that a particular invention is not possible years after the filing date, that would be evidence that the disclosed invention was not possible at the time of filing and should be considered. In *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513-14 (Fed. Cir. 1993). Accordingly, the variable CD44 immunoreactivity is highly relevant to the instant invention, contrary to Applicants' assertion.

Applicants argue that a population of astrocyte precursor cells that are at once A2B5 negative and CD44 positive is clearly demonstrated by data presented in Table 1 at page 7 of the instant application. Such is not found persuasive, because Table 1 simply presents a comparison between the cell markers of the presently claimed cells and some markers disclosed by the prior art of Barres et al. Further, the teachings of Barres et al. have not been cited by the Examiner as relevant to the instant rejection.

Applicants additionally argue that it is only the Examiner who has characterized Examples 1-5 as "working examples" not Applicants, and has improperly concluded that the disclosure is not enabling based on an analysis of only this factor while ignoring one or more of the others. Such is not found persuasive, because the examples have been considered along with the teachings of the prior art and the specification as a whole, concluding that the "other factors", such as the characteristics of the instantly claimed pure homogeneous population of mammalian astrocyte restricted precursor cells are not is not accord with the observations in the working examples, and the teachings of the prior art.

Applicants are requiring a person of skill in the art to ignore the examples, and only consider parts of the specification, such as Table 1 as providing an enabling disclosure, (Applicants have previously stated on the record, that these Examples were not provided as enablement for the instant claimed cells), when the specification states: "The following nonlimiting examples are provided to further illustrate the present invention." (p. 15, lines 14-15). As previously indicated, Applicants have essentially argued that a person of skill in the art should not regard the working Examples as enabling for the instantly claimed invention, and thus particularly ignore Example 2, titled: "Isolation of Human Neuroepithelial Precursor Cells", that includes the isolation of A2B5 negative cells. However, a person of skill in the art having considered the teachings of the entire specification, would not find sufficient guidance for

making the instantly claimed pure homogenous population of precursor cells that are at once A2B5 negative and CD44 positive, and restricted to only the astrocyte lineage, thus lacking the ability to generate oligodendrocytes. A person of ordinary skill having considered the teachings of the instant specification and the prior art would merely conclude that neuroepithelial precursor cells can differentiate into astrocytes, oligodendrocytes or other neural cells depending on culture conditions, and that any intermediate cell population of the final product (astrocytes) was not purified as a pure homogenous population of astrocyte restricted cells at the time of the instant invention by Applicants. As the initial neuroprogenitor cells and their differentiation to the end product (astrocytes) were known and described in the prior art, any potential intermediates in the differentiation process must necessarily also be present. However, as indicated in MPEP 2112, The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364,1368 (Fed. Cir. 2004).

Applicants further argue that the post-filing article by Liu et al. was submitted in lieu of an inventor Declaration as the article contains evidence confirming that CD44 identifies an astrocyte restricted precursor cell that is committed to generating astrocytes. Applicants cite MPEP 2164.01(b), that as long as the specification discloses at least one method of making and using the claimed invention that bears a reasonable correlation to the entire scope of the claims, then the enablement requirement of 35 U.S.C. 112, first paragraph, is satisfied.

Such is not found persuasive, because the pure homogeneous population of mammalian astrocyte restricted precursor cells that generate astrocytes under oligodendrocyte differentiation conditions fails to correlate with any of the methods of making the product exemplified in the specification. Moreover, the post-filing art of Liu et al. does not cure the deficiencies in the instant disclosure.

Applicants argue that while the Examiner is correct that Liu et al. describes a transgenic mouse model, this reference also shows that CD44+ astrocyte restricted precursor cells are present in the developing rodent spinal cord before the acquisition of GFAP immunoreactivity and in human fetal tissue. Such is not found persuasive, because the presence of such cells in the

post-filing art of Liu et al. is not commensurate with the scope of the instant claims, that require the astrocyte restricted cells to generate astrocytes under oligodendrocyte differentiation conditions of plating in a bFGF-containing medium for 2 days and then switching to a medium containing PDGF or exposure to PDGF and thyroid hormone. Furthermore, as is clear from their teachings on p. 34, Liu et al. were able to differentiate cells into astrocytes as assessed by GFAP transgene expression, that is dependent on the transgenic model. Moreover, as previously stated, the specification must be enabling as of the filing date. A later dated publication cannot supplement an insufficient disclosure in a prior dated application to make it enabling. MPEP 2164.05(a) states: "Specification Must Be Enabling as of the Filing Date". The state of the prior art provides evidence for the degree of predictability in the art and is related to the amount of direction or guidance needed in the specification as filed to meet the enablement requirement. The state of the prior art is also related to the need for working examples in the specification. The state of the art existing at the filing date of the application is used to determine whether a particular disclosure is enabling as of the filing date. *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1325-26 (Fed. Cir. 2004) ("a patent document cannot enable technology that arises after the date of application"). Publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the time of filing. *In re Gunn*, 537 F.2d 1123, 1128, 190 USPQ 402,405-06 (CCPA 1976); *In re Budnick*, 537 F.2d 535, 538, 190 USPQ 422, 424 (CCPA 1976).

It is additionally noted that the post-filing art of Liu et al. describes using a CD44 misexpression transgenic mouse model and the misexpression of CD44 in culture to inhibit oligodendrocytes and arrest cells at the precursor state, thus providing evidence for the existence of CD44+ astrocyte-restricted precursor cells in the developing nervous system (Abstract). Thus, Liu et al. did not demonstrate a pure homogenous population of astrocyte-restricted precursor cells in the absence of CD44 misexpression.

As the teachings of the disclosure by Applicants fails to meet the limitations of the instant claims, and the prior art does not teach an astrocyte restricted precursor cell that does not generate oligodendrocytes, a person of skill in the art would need to engage in additional experimentation to develop the methodologies for discovering an astrocyte restricted precursor

cell. Such further experimentation is regarded as undue and unpredictable, in view of the absence of sufficient guidance in either the instant specification or the prior art.

Therefore, the rejection of claims 1-4 is maintained in modified form, for reasons of record and the preceding discussion.

Response to Claim Rejections - 35 USC § 102

Claims 1-4 stand rejected under 35 U.S.C. 102(e) as being anticipated by Carpenter (U.S. Patent No.: 6,833,269; filed May 31, 2001). The rejection set forth on pp. 8-10 of the previous office action dated March 12, 2007, and pp. 5-6 of the office action dated November 1, 2007 is maintained for reasons of record.

The instant claims embrace a pure homogenous population of mammalian precursor cells isolated from mammalian embryonic or fetal tissue or mammalian embryonic stem (ES) cells cultures, being CD44 immunoreactive that may be differentiated to generate astrocytes. The claim language of "astrocyte restricted" is interpreted to be non-limiting because the ability of the cells to differentiate into astrocytes, but not oligodendrocytes is a consequence of culturing conditions, as taught by the instant specification (Example 3, p. 17). Moreover, a precursor cell treated under differentiating conditions would necessarily become committed to a particular differentiation path of cell specific lineage, immediately prior to terminal differentiation.

The prior art of Carpenter has been applied commensurate with the enabled scope of the claims indicated above and to the extent that the claims embrace a population of mammalian precursor cells isolated from mammalian embryonic stem (ES) cells cultures, that may be differentiated to generate astrocytes.

Carpenter teaches methods for producing neural progenitor cells by culturing, expanding and differentiating embryonic stem cells into a variety of different neural phenotypes in a cocktail of growth conditions (Abstract). Specifically, human embryonic stem cells (hES) are maintained in a feeder-free system on plates coated with Matrigel® in medium composed of 80% KO DMEM (knockout) and 20% serum replacement medium supplemented with 1% non-essential amino acids, 1mM glutamine, 0.1 mM β-mercaptoethanol and 4ng/ml bFGF, (the media conditioned by culturing embryonic fibroblasts) (column 21). The cells are expanded by serial

passaging, removed and used formation of embryoid bodies (column 21). Following immunosorting and magnetic separation, the "cells are maintained on plates coated with poly-lysine and laminin in DMEM/F12 (Biowhittaker) supplemented with N2 (Gibco 17502-014), B27 (Gibco 17504-010) and the factors indicated. Source of the factors is shown in Table 2." (column 22). In Example 5, Carpenter et al. teach: "To generate terminally differentiated neurons, the first stage of differentiation was induced by forming embryoid bodies in FBS medium with or without 10 μM retinoic acid (RA). After 4 days in suspension, embryoid bodies were plated onto fibronectin-coated plates in defined medium supplemented with 10 ng/mL human EGF, 10 ng/mL human bFGF, 1 ng/mL human PDGF-AA, and 1 ng/mL human IGF-1. After 3 days, many cells with neuronal morphology were observed. The neural precursors were identified as cells positive for BrdU incorporation, nestin staining, and the absence of lineage specific differentiation markers. Putative neuronal and glial progenitor cells were identified as positive for polysialylated NCAM and A2B5…The cell populations were further differentiated by replating the cells in a medium containing none of the mitogens, but containing 10 ng/mL Neurotrophin-3 (NT-3) and 10 ng/mL brain-derived neurotrophic factor (BDNF). Neurons with extensive processes were seen after about 7 days." (column 28). The method of Carpenter provides for the differentiation of pluripotent ES cells into cells of the neuronal or glial lineage. Precursor cells for either lineage, provide a source for generating additional precursor cells, neurons, astrocytes or oligodendrocytes (column 3; first paragraph), as well as neurons that include glial cells, astrocytes, dopaminergic cells and motor neurons (Abstract, column 19 and claim 18).

While markers such as A2B5 are discussed by Capenter et al., CD44 immunoreactivity was not assessed by the authors. However, as stated above, CD44 expression is variable, and apparently dependent on serum concentration and culture conditions. Further the expression of CD44 is an inherent feature of the mammalian ES cell derived precursor cells of Carpenter et al. and must necessarily be present under the culture conditions of the instant invention. As stated in MPEP 2112: The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. "The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir.1995) (affirmed a 35 U.S.C. 103

rejection based in part on inherent disclosure in one of the references). See also *In re Grasselli*, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983).

Moreover, "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Applicants traverse the rejection, arguing the claims have been amended to recite that the astrocyte-restricted precursor cells generate astrocytes but not oligodendrocytes under oligodendrocyte differentiation conditions of plating in a bFGF-containing medium for 2 days and then switching to a medium containing PDGF or exposure to PDGF and thyroid hormone, and Carpenter does not teach astrocyte-restricted precursor cells which generate astrocytes but not oligodendrocytes under oligodendrocyte differentiation conditions. Applicants' arguments have been fully considered, but are not found persuasive.

As indicated, the rejection of the claims over the prior art of Carpenter et al. is applicable to the enabled scope of the invention, and not to the oligodendrocyte differentiating conditions, that the instant specification has expressly disclosed as differentiating oligodendrocytes, not astrocytes. Further, as previously indicated, the limitation for astrocyte-restricted neuroprogenitor cells is not afforded patentable weight in view of the foregoing discussion.

Applicants state Carpenter arguably teaches away from such a cell population since their A2B5 positive cells generated oligodendrocytes, astrocytes and neurons (see Example 3 of Carpenter). Accordingly, the instant claimed invention is also not inherent in teachings of Carpenter. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., A2B5) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, the generation of oligodendrocytes, astrocytes and neurons are dependent on culture conditions, in a similar manner disclosed in the

Applicants' specification. Moreover, Applicants' attempt to rebut Carpenter's description of the cells as a teaching away is mis-applied, as the instant rejection over the prior art is for anticipation, and not obviousness.

Carpenter teaches methods for producing neural progenitor cells by culturing, expanding and differentiating embryonic stem cells into a variety of different neural phenotypes in a cocktail of growth conditions (Abstract). The method of Carpenter provides for the differentiation of pluripotent ES cells into cells of the neuronal or glial lineage. Precursor cells for either lineage, provide a source for generating additional precursor cells, neurons, astrocytes or oligodendrocytes (column 3; first paragraph), as well as neurons that include glial cells, astrocytes, dopaminergic cells and motor neurons (Abstract, column 19 and claim 18). Additionally, CD44 expression is variable, and apparently dependent on serum concentration and culture conditions. Further the expression of CD44 is an inherent feature of the mammalian ES cell derived precursor cells of Carpenter et al. and must necessarily be present depending on the culture conditions.

Therefore, the rejection of claims 1-4 is maintained for reasons of record and the preceding discussion.

Conclusion

Claims 1-4 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREYDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fereydoun G Sajjadi/

Fereydoun G. Sajjadi, Ph.D.
Examiner, Art Unit 1633